

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

THE MEDICINES COMPANY,	)	
	)	
	)	
Plaintiff,	)	
	)	Case No. 11-cv-1285
v.	)	
	)	
MYLAN INC., MYLAN	)	
PHARMACEUTICALS INC., and	)	
BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

**REDACTED MEMORANDUM OPINION AND ORDER**

AMY J. ST. EVE, District Court Judge:

Before the Court is The Medicine Company's ("TMC") motion to dismiss and strike Defendant Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC's (collectively, "Mylan") inequitable conduct and unclean hands counterclaims and affirmative defenses. For the following reasons, the Court grants TMC's motion in part and denies it in part.

**PROCEDURAL BACKGROUND**

On February 23, 2011, TMC filed its Complaint against Mylan, alleging infringement of U.S. Patent Nos. 7,582,727 (the "'727 Patent") and 7,598,343 (the "'343 Patent"), both of which pertain to pharmaceutical formulations of bivalirudin and the processes of making bivalirudin. (R. 1, Complaint.) The '727 Patent, entitled "Pharmaceutical formulations of bivalirudin and the processes of making the same," was issued on September 1, 2009 to TMC upon assignment from Gopal Krishna and Gary Musso, the named inventors (collectively, the "Applicants"). (*Id.* ¶ 12.) The '343 Patent, entitled "Pharmaceutical formulations of bivalirudin and the processes of

making the same,” was issued on October 6, 2009 to TMC upon assignment from Krisha and Musso.<sup>1</sup> TMC markets bivalirudin through its brand name, Angiomax®. (*Id.* ¶ 13.)

Angiomax® is an anticoagulant drug used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (*Id.* ¶ 11.)

The ‘727 and ‘343 Patents are listed in the U.S. Food and Drug Administration (“FDA”) publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”) as covering TMC’s Angiomax® product. (*Id.* ¶ 14.) TMC alleges that Mylan prepared and submitted an Abbreviated New Drug Application (“ANDA”) to the FDA under § 505(j) of the Food, Drug, and Cosmetic Act (“FDCA”), seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic bivalirudin, 250 mg/vial, for intravenous injection (“Mylan’s Proposed Product”) before expiration of the ‘727 and ‘343 Patents. (*Id.* ¶ 15.) TMC further avers that Mylan’s ANDA includes a “paragraph IV certification.”<sup>2</sup> (*Id.* ¶¶ 22, 32.) TMC asserts that 1) Mylan infringed the ‘727 and ‘343 Patents by including a paragraph IV certification to both patents in its ANDA;

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<sup>1</sup> The ‘727 and ‘343 Patents are at times referred to collectively as the “patents-in-suit” in this Memorandum Opinion and Order.

<sup>2</sup> A company that submits an ANDA for FDA approval must “make a certification addressing each patent listed in the Orange Book that claims the drug,” stating that “(I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted.” *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002) (citing 21 U.S.C. § 355(j)(2)(A)(vii) (I-IV)). “When an ANDA contains a paragraph IV certification,” as here, “the ANDA applicant must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is not infringed, invalid, or unenforceable.” *Id.* (citing 21 U.S.C. § 355(j)(2)(B)(I) and 21 C.F.R. § 314.95(c)(6)). “The patentee then has forty-five days to sue the ANDA applicant for patent infringement.” *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

2) Mylan's Proposed Product infringes at least claims 1-10 of the '727 Patent and at least claims 1-11 of the '343 Patent because Mylan's Notice Letter does not include a paragraph IV certification asserting non-infringement of those claims; and 3) Mylan will commercially manufacture, sell, offer for sale, and/or import Mylan's Proposed Product immediately upon FDA approval, which warrants injunctive relief. (*Id.* ¶¶ 23, 25, 27, 33, 35, 37.)

On December 19, 2011, Mylan filed its First Amended Answer, Separate Defenses and Counterclaims, in which it asserts a number of affirmative defenses and counterclaims, including an affirmative defense of unenforceability due to inequitable conduct for both the '727 and '343 Patents (Tenth Affirmative Defense), an affirmative defense of unenforceability due to unclean hands as to both patents (Eleventh Affirmative Defense), counterclaims for unenforceability due to inequitable conduct as to both patents (Seventh and Eighth Counterclaims), and counterclaims for unenforceability due to unclean hands as to both patents (Ninth and Tenth Counterclaims). (R. 62, Answer.) Mylan alleges that TMC and Applicants intentionally misrepresented and failed to disclose methodology and experimental results that were highly material to the patentability of the '727 and '343 Patents. It further avers that the Applicants intentionally failed to disclose to the U.S. Patent and Trademark Office ("PTO") the identities of the true inventors of the patents-in-suit. (*Id.*)

TMC moves to strike Mylan's unclean hands and inequitable conduct affirmative defenses and dismiss Mylan's unclean hands and inequitable conduct counterclaims pursuant to Federal Rules of Civil Procedure ("Rule") 12(b)(6) and 12(f), respectively, arguing that Mylan fails to 1) allege requisite facts supporting an inference of an intent to deceive; 2) identify the

requisite claim limitations to which the alleged material is relevant; and 3) allege a legally cognizable claim for unclean hands.

### FACTUAL BACKGROUND<sup>3</sup>

#### I. Angiomax®

This case involves two patents related to an anti-coagulant drug called Angiomax®. Angiomax® is the trade name for bivalirudin, 250 mg/vial, for intravenous injection, and it is approved by the FDA for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. (R. 62 ¶ 42.)<sup>4</sup> TMC is the owner of New Drug Application (“NDA”) No. 20-873, which the FDA has approved for the manufacture and sale of Angiomax®. (*Id.* ¶ 11.) TMC has been marketing Angiomax® since 2001. (*Id.*)

Angiomax® is supplied in single-use vials as a sterile lyophilized cake. Each vial contains 250 mg bivalirudin peptide, 125 mg mannitol (a sugar), and sodium hydroxide (a base) to adjust the pH to 5-6. (*Id.* ¶ 43.) It also contains trace impurities that are generated during the synthesis of the bivalirudin peptide, during formulation of the finished Angiomax® product,

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<sup>3</sup> The parties filed their briefs under seal (and also filed redacted versions publicly), asserting that the briefs contain confidential information pursuant to the parties’ protective order. *See* R. 64. Having reviewed the parties’ briefs, both parties were overly-zealous in their redactions. In the Seventh Circuit, “[i]nformation that affects the disposition of litigation belongs in the public record unless a statute or privilege justifies nondisclosure.” *United States v. Foster*, 564 F.3d 852, 853 (7th Cir. 2009). “[S]ecrecy is fine at the discovery stage, before the material enters the judicial record. But those documents, usually a small subset of all discovery, that influence or underpin the judicial decision are open to public inspection unless they meet the definition of trade secrets or other categories of bona fide long-term confidentiality.” *Id.* (internal citations and quotation marks omitted). The patents-in-suit, which describe the relevant processes for making bivalirudin at issue, and the FDA’s Orange Book listing for Angiomax® are publicly available.

<sup>4</sup> For purposes of this motion, the Court must assume all well-pleaded facts in the counterclaims as true. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011).

and/or during storage. (*Id.* ¶ 44 (citing the ‘727 patent at 2:1-19).) One such trace impurity is called Asp<sup>9</sup> - bivalirudin. (*Id.*)

The FDA regulates the amount of trace impurities in Angiomax®, including Asp<sup>9</sup> - bivalirudin. (*Id.* ¶ 45.) The FDA regulatory specifications for Angiomax® also set restrictions on certain of its physical characteristics, including the time in which it takes the sterile lyophilized cake to reconstitute in an aqueous solution prior to use. (*Id.*) Before TMC may market the Angiomax® product in the United States, it must undergo release testing to ensure compliance with the above FDA specifications. (*Id.* ¶ 47.) If the product does not meet those specifications, it is “out-of-specification” (“OOS”), and TMC cannot market it in the United States. (*Id.* ¶ 47.) The FDA also requires that manufacturers use written procedures in drug production to ensure that drug products have the identity, strength, quality, and purity they purport to have. (*Id.* ¶ 48.) Such procedures may include the use of batch records. (*Id.*) A “Master Production Batch Record” (“MPR”) is a detailed, step-by-step description of the entire production process for a specific drug. A fill-in-the-blank version of the MPR that is used when manufacturing individual drug batches is called a “Production Batch Record.” (*Id.*)

Ben Venue Laboratories (“BVL”) has been the sole manufacturer of Angiomax® since at least 1997. (*Id.* ¶¶ 49-50.) It also tests, packages, and releases Angiomax® on behalf of TMC. (*Id.* ¶ 49.) From November 1997 to May 2005, BVL manufactured over 80 lots or batches of Angiomax® on behalf of TMC, and during that time, all batches met the FDA’s specification requirements for Asp<sup>9</sup> - bivalirudin levels, total impurity levels, and reconstitution times. (*Id.* ¶ 50.)

## **II. Angiomax® Manufacturing Process from 2005 to 2009**

### **A. The 2005 Report**

On June 22, 2005, BVL's quality control group obtained an OOS Asp<sup>9</sup> - bivalirudin level of 3.9% during initial release testing of Angiomax® Lot 716184, exceeding the FDA regulatory specification. (R. 62 ¶ 51.) Shortly thereafter, BVL launched an investigation into Lot 716184 to determine why it had unusually high Asp<sup>9</sup> - bivalirudin levels. (*Id.* ¶ 52.) The investigation culminated in a quality investigation report that BVL's representatives signed and approved approximately six months later (the "2005 Report"). (*Id.* ¶ 53.) A copy of the 2005 Report was emailed to TMC on or before January 27, 2006. (*Id.* ¶ 54.) TMC produced a copy of the 2005 Report, which contains numerous handwritten annotations, from the files of named inventor Musso during the course of this litigation. (*Id.*)

The 2005 Report indicates that BVL learned in discussions with TMC that high pH conditions may lead to the formulation of excess Asp<sup>9</sup> - bivalirudin levels. (*Id.* ¶ 55.) According to the report, "[TMC] expressed particular interest in Step 12 of the Compounding Instructions" during those discussions. (*Id.*) Step 12 of the 2005 MPR described a manufacturing step that relates to how a base is mixed together with bilvalirudin and mannitol—one of the central issues in the parties' current dispute. (*Id.* ¶ 56.) Specifically, the 2005 Report provided that "[i]f too much of the [base] solution [is] added to the formulation vessel, the final pH of the bulk solution could be too high. According to [TMC], this could potentially cause degradation of the [bivalirudin] and increase the level of the [Asp<sup>9</sup>] impurity." (*Id.* ¶ 57.)

The 2005 Report pinpointed the excess Asp<sup>9</sup> - bivalirudin formation on the lack of specification direction in Step 12 of the 2005 MPR. (*Id.* ¶ 58.) Specifically, it noted that Step 12

gave BVL operators (i.e., BVL employees who make Angiomax® by implementing the MPR) too much discretion in adding base:

In first preparing to formulate the Part III [compounding] solution, the MPR requires two mixers to be set up in Vessel #3. In steps earlier than Step #12, these mixers are initially set at a rate of 400-600 RPM. Immediately after adding the necessary portion of [the base solution] at Step 12, the mix rate for the two mixers in Vessel #3 is to be increased to aid dispersion of the [base] solution. The mix rate is to be increased from a range of 400-600 RPM to a range of 900-1300 RPM. The MPR requires the necessary amount of [base] solution to be added "QUICKLY and ALL AT ONCE."

...

There is a challenge in adding the [base] solution quickly and all at once, given the volume of the solution to be added . . . . BVL formulators have historically employed different means of adding the solution when compounding Bivalirudin lots. Note that the MPR does not specific [sic] how to add the Part II solution. The means of addition vary from operator to operator. However, Formulations Supervision explained that three main methods are used to add the [base] solution[, including]

...

- 3) The [base] solution vessel (#2) is fitted with a drain hose . . . . The pressure forces the [base] solution through the hose, which is directed into Vessel #3.

For the formulation lot 716184, BVL Formulations supervision stated that the third method was used; *i.e.*, the [base] solution was pressurized/forced into Vessel #3 . . . .

(*Id.* ¶ 58.) The 2005 Report proposed revising Step 12 to standardize the addition of the pH-adjusting solution across operators:

Corrective Action/Preventative Action (CAPA)

We . . . developed specific instructions on how to add the [base] solution to Step 12.

. . . BVL Formulations will be required to distribute the necessary portion of [base] solution into smaller . . . aliquots. These smaller

portions will then be added successively at Step 12 of the formulation. This will better standardize the addition of the [base] solution at what is considered a critical step involving the pH of the bulk solution.

(*Id.* ¶ 59.) TMC and BVL formally approved the 2005 Report's proposed changes to the MPR on or before December 13, 2005. (*Id.* ¶ 60.)

**B. July 14, 2006 Meeting and the New Compounding Process**

BVL implemented the revised process on January 6, 2006 with the manufacture of Lot 716189. (*Id.* ¶ 61.) BVL made at least six Angiomax® batches using the revised compounding process between January 6, 2006 and June 17, 2006. (*Id.*) BVL's quality control group reported in 2006 that one of the seven lots TMC made using the revised compounding process, Lot 896002, failed to pass initial release testing because it contained excess levels (2.3%) of Asp<sup>9</sup>-bivalirudin. (*Id.* ¶ 62-63.)

TMC and BVL held a meeting on July 14, 2006 during which they discussed the formulation of bivalirudin in detail. (*Id.* ¶ 64.) TMC hired Musso as a consultant to "provide support to the team to get [sic] the root cause" of the Asp<sup>9</sup> - bivalirudin failures, and Musso attended the July 14 meeting. (*Id.*) On July 15, 2006, Musso prepared a summary of the July 14 meeting (the "July Meeting Summary"), a copy of which TMC produced in the Delaware Litigation<sup>5</sup> from Krishna's files. (*Id.* ¶ 66.) In the July Meeting Summary, Musso acknowledged that "[i]n 2005 a similar [Asp<sup>9</sup>] batch failure had occurred," and in response to that failure, BVL had taken "corrective actions. . . to add more control to the manufacturing process batch record,

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<sup>5</sup> TMC sued several other companies regarding the same patents in the United States District Court for the District of Delaware in 2009 and 2010. Those cases were consolidated for pre-trial purposes under Case No. 09-750 (the "Delaware Litigation").

mainly in the formulation and equipment use areas.” (*Id.* ¶ 65.) He also acknowledged that TMC and BVL had amended the MPR in 2005 “to improve the instructions for the base addition as a review at that time indicated that base could be added by a pump, poured in or dumped in at variable rates.” (*Id.*)

Musso recorded a few of the BVL operators’ experienced-based comments on how to improve the compounding process. Those comments include the following:

- Increase the stir speed prior to base addition.
- Add base through a dip tube so that it is dispersed in the bottom of the tank where mixing is still possible . . . .

(*Id.* ¶ 68.) After the July 14 meeting, TMC and BVL revised the MPR to incorporate the BVL operators’ suggestions from the meeting. This new compounding process (the “New Compounding Process”) later formed the basis for the patents-in-suit. (*Id.* ¶ 69.)

### **C. The 2007 Report**

BVL made approximately 60 Angiomax® batches between October 31, 2006 and October 6, 2009 using the New Compounding Process. (*Id.* ¶ 71.) During that time period, BVL rejected two Angiomax® batches due to excessive Asp<sup>9</sup>-bivalirudin levels. (*Id.* ¶ 72.) The first was Lot 1116050, which BVL manufactured on August 29, 2007. That lot had an Asp<sup>9</sup>-bivalirudin level of 12.4%, which far exceeded the FDA regulatory specification. (*Id.* ¶¶ 71-72.) BVL investigated the cause of the Asp<sup>9</sup>-bivalirudin failure, which culminated in a quality investigation report that BVL signed and approved approximately five months after the manufacture date (the “2007 Report”). The 2007 Report described the cause of the Asp<sup>9</sup>-bivalirudin failure as “operator error”:

Historically, over 100 lots of Bivalirudin have been manufactured at BVL with typical Asp9 results ranging 0.3%-0.6%. Two previous Bivalirudin lots (from 2005 and 2006) were rejected for high FP Asp9 results; these results were 2.3% and 3.6%. The atypically high OOS result of 12% suggests gross operator error occurred.

(*Id.* ¶ 75.) A copy of the 2007 Report was emailed to TMC on or before February 22, 2008. A draft version of the 2007 Report was emailed to Musso and Krishna on or before January 16, 2008. (*Id.* ¶ 76.)

REDACTED - CONFIDENTIAL INFORMATION

### III. TMC's Angiomax® Patent Applications

TMC and/or Krisha and Musso filed applications for the patents-in-suit on July 27, 2008 (the "Applications"), and on that same day, named inventors Musso and Krishna filed declarations signed under penalty of perjury acknowledging that they owed a duty to disclose to the PTO all information they knew to be material to patentability. (*Id.* ¶ 82.) Musso and Krishna also assigned their right, title and interest in the patents-in-suit to TMC. (*Id.* ¶ 83.) All patent claims of the patents-in-suit are directed toward "pharmaceutical batches"<sup>6</sup> of Angiomax® having either (1) "a maximum impurity level of Asp<sup>9</sup>-bivalirudin that does not exceed about 0.6% as measured by HPLC"; or (2) "a maximum reconstitution time that does not exceed about 42 seconds and a maximum total impurity level that does not exceed about 2% as measured by HPLC." (*Id.* ¶ 84.)

In their communications with the PTO, Musso and Krishna argued that they had invented "more consistent" Angiomax®, representing a "significant advance" over prior art Angiomax® that was on sale more than one year before they filed the patent applications. (*Id.* ¶ 86.) Central to their argument was TMC's contention that the patents-in-suit disclosed the New Compounding Process, which differed from TMC's "old compounding process" in two fundamental ways. (*Id.*)

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<sup>6</sup> The specification of the patents-in-suit defines the term "pharmaceutical batch" as "material produced by a single execution of a compounding process of various embodiments of the present invention. 'Batches' or 'pharmaceutical bathes' as defined here may include a single batch, wherein the single batch is representative of all commercial batches . . . and wherein the levels of, for example, Asp<sup>9</sup> bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent levels for all potential batches made by said process. 'Batches' may also include all batches prepared by a same compounding process." (*Id.* ¶ 85 (citing '727 Patent a 5:24-36).)

First, Musso and Krishna contended that they developed the New Compounding Process, which was characterized by “efficient mixing” involving pumping a base solution of sodium hydroxide into a solution of the active pharmaceutical ingredient (bivalirudin) through a “feed tube,” and then providing a “high shear mixing environment (between about 1000 rpm and 1300 rpm).” (*Id.* ¶ 87.) Second, Musso and Krishna asserted that claimed Angiomax®, as made by the New Compounding Process, differed from prior art Angiomax® because it was “more consistent” and “[had] a maximum level of Asp<sup>9</sup>-bivalirudin of about 0.6% . . . , a maximum reconstitution time of about 42 seconds . . . , and a maximum amount of total impurities of about 2.0% . . . , for all batches or formulations made by the new process.” (*Id.* ¶ 88.)

On at least three separate occasions, the Patent Examiner rejected all proposed claims in the Applications for the patents-in-suit as anticipated and/or obvious in view of the prior art. (*Id.* ¶ 89.) Among the reasons for the Patent Examiner’s rejections was that the prior art bivalirudin products “necessarily have all the characteristics and functionalities of the instantly claimed products.” (*Id.* ¶ 89.) Musso and Krishna argued against the Patent Examiner’s rejections, relying heavily upon experimental results from two “studies” described in detail in the patents-in-suit. (*Id.* ¶ 90 (citing “Example 4” and “Example 5” in the ‘727 Patent at 21:44-24:35).)

**A. The “Example 4 Study”**

In Example 4 of the ‘727 Patent, Musso and Krishna described a “study” in which 89 Angiomax® batches were manufactured and analyzed for impurity levels and reconstitution times. (*Id.* ¶ 91.) TMC has admitted that the Angiomax® batches described in Example 4 were made between November 6, 1997 and June 17, 2006. (*Id.*) TMC’s commercial distributor of Angiomax® produced internal records in this litigation showing that these same batches were

sold, marketed, or offered for sale more than one year prior to the filing of the patents-in-suit.

(*Id.*) The patents-in-suit describe the methodology of the Example 4 study as follows:

The effects of rapidly adding the pH-adjusting solution to the bivalirudin solution under slow mixing conditions were studied. Multiple batches were generated by the same method. . .

The pH-adjusting solution was added to the bivalirudin solution either all at once, or rapidly in multiple portions, while the bivalirudin solution was mixed by two paddle mixers located at the top and bottom of the bivalirudin solution. Both paddle mixers operated at a rate of between about 400 and about 800 rpm.

(*Id.* ¶ 92 (citing '727 patent at 21:50-64).)

The patents-in-suit describe the characteristics of the batches generated by the methodology used in the Example 4 study batches--specifically stating that the maximum Asp<sup>9</sup>-bivalirudin level was 3.6%, the maximum total impurity level was 3.0%, and the maximum reconstitution time was 72 seconds. (*Id.* ¶ 93.)

**B. The "Example 5 Study"**

Musso and Krishna described a separate "Example 5 Study" in the patents-in-suit, in which 25 Angiomax® batches were manufactured and analyzed for impurity levels and reconstitution times. (*Id.* ¶ 95.) The specification describes the Example 5 Study as follows:

The effects of adding the pH-adjusting solution to the bivalirudin solution at a constant rate and under efficient mixing condition [sic] were studied. Multiple batches were generated by the same method. . .

The pH-adjusting solution was added to the bivalirudin solution at a controlled rate of 2L/min using a peristaltic pump. A homogenizer was used to provide a high shear mixing environment (between 1000 rpm and 1300 rpm) . . . . A feed tube extended from the peristaltic pump to an inlet in the homogenizer, so that the pH-adjusting solution was added to the bivalirudin solution at a

side adjacent to the blades of the homogenizer. (*Id.* ¶ 96 (citing ‘727 Patent at 22:37-56).)

The patents-in-suit state that the maximum Asp<sup>9</sup>-bivalirudin level was 0.6%, the maximum total impurity level was 2.0%, and the maximum reconstitution time was 42 seconds. (*Id.* ¶ 97 (citing ‘727 Patent at 23:1-13).) Example 5 in the patents-in-suit was the only experimental evidence Musso and Krishna submitted to the PTO purporting to show that they possessed the claimed invention. (*Id.* ¶ 98.)

### **C. Musso and Krishna’s Arguments to the PTO**

In an attempt to convince the Patent Examiner that the claimed Angiomax® was patentable over prior art Angiomax®, Krishna and Musso compared and contrasted Angiomax® made by the Example 4 process (the “Old Compounding Process”) with the Example 5 process (which was the same as the New Compounding Process). (*Id.* ¶ 99.) They told the PTO that the Old Compounding Process used “inefficient mixing” that resulted in inconsistent and/or high maximum impurity levels and reconstitution times, whereas the New Compounding Process uses “efficient mixing” that resulted in consistently low maximum impurity levels and/or reconstitution times. (*Id.* (citing multiple specific statements).) They also relied on arguments that Musso made in his 37 C.F.R. § 1.132 declaration, wherein he represented that claimed Angiomax® had maximum Asp<sup>9</sup>-bivalirudin levels not exceeding about 0.6% and maximum reconstitution times not exceeding about 42 seconds. (*Id.* ¶ 100.) In response to these arguments, the Patent Examiner allowed the claims to issue, finding that Angiomax® “hav[ing] a maximum impurity level of Asp<sup>9</sup>-bivalirudin that does not exceed 0.6%, and wherein the maximum total impurity level does not exceed about 2% [was] both novel and free of prior art.” (*Id.* ¶ 102.)

## LEGAL STANDARD

### I. Rule 12(b)(6)

Although this is a patent case, the Court applies the Seventh Circuit's Rule 12(b)(6) standard. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009) (regional circuit law applies to procedural issues that are not specific to patent law); *see also Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) ("This court reviews the dismissal of a claim under Rule 12(b)(6), a matter of procedure, by applying the law of the regional circuit."). "A motion under Rule 12(b)(6) challenges the sufficiency of the complaint to state a claim upon which relief may be granted." *Hallinan v. Fraternal Order of Police of Chicago Lodge No. 7*, 570 F.3d 811, 820 (7th Cir. 2009). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *AnchorBank*, 649 F.3d at 614 (internal quotation marks and citation omitted). "In evaluating the sufficiency of the complaint," the court must "view it in the light most favorable to the plaintiff, taking as true all well-pleaded factual allegations and making all possible inferences from the allegations in the plaintiff's favor." *Id.* (citing *Wilson v. Price*, 624 F.3d 389, 391 (7th Cir. 2010)). To survive a Rule 12(b)(6) motion, "the complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Indep. Trust Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 934-35 (7th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (internal quotation marks omitted)). It is not enough to put "a few words on paper that, in the hands of an imaginative reader, *might* suggest that something has happened to her that *might* be

redressed by the law.” *AnchorBank*, 649 F.3d at 614 (citing *Swanson v. Citibank, N.A.*, 614 F.3d 400, 403 (7th Cir. 2010) (emphasis in original)).

## **II. Rule 12(f)**

Pursuant to Rule 12(f), the Court “may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed.R.Civ.P. 12(f); *Delta Consulting Grp., Inc. v. R. Randle Constr., Inc.*, 554 F.3d 1133, 1141 (7th Cir. 2009).

“Affirmative defenses will be stricken ‘only when they are insufficient on the face of the pleadings.’” *Williams v. Jader Fuel Co., Inc.*, 944 F.2d 1388, 1400 (7th Cir. 1991) (quoting *Heller Fin. v. Midwhey Powder Co.*, 883 F.2d 1286, 1294 (7th Cir. 1989)); *Sloan Valve Co. v. Zurn Indus., Inc.*, 712 F. Supp.2d 743, 749 (N.D. Ill. 2010). “Motions to strike are not favored and will not be granted unless it appears to a certainty that plaintiffs would succeed despite any state of the facts which could be proved in support of the defense.” *Williams*, 944 F.2d at 1400 (internal quotation marks and citations omitted). Yet, “[i]t is appropriate for the court to strike affirmative defenses that add unnecessary clutter to a case.” *Davis v. Elite Mortg. Servs.*, 592 F. Supp.2d 1052, 1058 (N.D. Ill. 2009) (citing *Heller*, 883 F.2d at 1295). “It is also true that because affirmative defenses are subject to the pleading requirements of the Federal Rules of Civil Procedure, they must set forth a ‘short and plain statement’ of all the material elements of the defense asserted; bare legal conclusions are not sufficient.” *Id.* (citing *Heller*, 883 F.2d at 1294; Fed.R.Civ.P. 8(a); *Renalds v. S.R. G. Rest. Grp.*, 119 F. Supp.2d 800, 802 (N.D. Ill. 2000)). District courts have considerable discretion under Rule 12(f). *See Delta*, 554 F.3d at 1141-42.

## ANALYSIS

### I. Inequitable Conduct Affirmative Defenses and Counterclaims

“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability. . . .” 37 C.F.R. § 1.56(a); *see also Honeywell Int’l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007). “A breach of this duty—including affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information—coupled with an intent to deceive, constitutes inequitable conduct.” *Honeywell*, 488 F.3d at 999 (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)). In order to plead a claim for inequitable conduct, Mylan must allege that “(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1327, n.3 (citations omitted).

Although inequitable conduct is a “broader concept than fraud,” it is well established Federal Circuit law that a party must plead inequitable conduct with particularity under Rule 9(b). *See Exergen*, 575 F.3d at 1326-27; *Ferguson Beauregard/Logic Controls*, 350 F.3d at 1344; *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356-57 (Fed. Cir. 2007). Federal Circuit law applies to the issue of whether Mylan’s allegations of inequitable conduct meet Rule 9(b)’s heightened pleading requirements. *Exergen*, 575 F.3d at 1318 (“Whether inequitable conduct has been pleaded with particularity under Rule

9(b) is a question governed by Federal Circuit law.”) (citing *Cent. Admixture*, 482 F.3d at 1356)). Rule 9(b) requires that a plaintiff plead “the circumstances constituting fraud” with “particularity,” although “[m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed.R.Civ.P. 9(b). “A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” *Exergen*, 575 F.3d at 1326-27 (citing *King Auto., Inc. v. Speedy Muffler King, Inc.*, 667 F.2d 1008, 1010 (CCPA 1981)).

In *Exergen*, the Federal Circuit articulated the substantive pleading requirements for inequitable conduct claims. Similar to fraud cases, in order to satisfy Rule 9(b)’s particularity requirements, the pleading must set forth the “who, what, when, where, and how” of the “material misrepresentation or omission committed before the PTO.” *Id.* at 1327. Although the party asserting the counterclaim may aver knowledge and intent generally, “a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive.” *Id.* at 1328-29. “A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith.” *Id.* at 1329, n.5.

Almost two years after *Exergen*, the Federal Circuit issued *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), in which it tightened the proof requirements with respect to the materiality and intent elements of an inequitable conduct claim.

*Id.* at 1285.<sup>7</sup> *Therasense* did not address inequitable conduct claims at the pleading stage, nor did it override *Exergen*'s pleading requirements. *See Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) (affirming that, post-*Therasense*, "[a] charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff's complaint recites facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO") (citing *Exergen*, 575 F.3d at 1318, 1330; citing generally *Therasense*); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F. Supp.2d 409, 432 (E.D. Va. 2011) ("*Exergen* still states the correct elements required for pleading inequitable conduct after *Therasense*."); *but see Hansen Mfg. Corp. v. Enduro Sys., Inc.*, No. CIV. 11-4030, 2011 WL 5526627, at \*4 (D.S.D. Nov. 14, 2011) ("*Therasense* tightened the standards for pleading inequitable conduct. . .").

That said, *Therasense* made clear that district courts may no longer assess allegations of materiality by the "reasonable examiner" or PTO Rule 56 standard. Instead, "in assessing the materiality of a withheld reference," the court must determine whether there are sufficient allegations from which a court may reasonably infer that "the PTO would not have allowed the claim if it had been aware of the undisclosed prior art." *See Therasense*, 649 F.3d at 1291-94 (rejecting the relatively broad "reasonable examiner" and PTO Rule 56 materiality standards and holding that inequitable conduct claims based on "nondisclosure of prior art references to the

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<sup>7</sup> The Federal Circuit, in both *Therasense* and *Exergen*, expressed concern with the frequency with which parties assert inequitable conduct claims. Indeed, the court announced that it undertook review of the panel's decision in *Therasense* at least in part because it recognized "the problems created by the expansion and overuse of the inequitable conduct doctrine." *Id.* at 1285.

PTO” or “failure to mention prior art references” must allege “but for” materiality); *Capital Mach. Co., Inc. v. Miller Veneers, Inc.*, No. 09-cv-702, 2012 WL 243563, at \*3 (S.D. Ind. Jan. 25, 2012) (noting that after *Therasense*, “materiality requires that the patent would not have issued but for the misrepresentation”); *Recticel Automobilesysteme GMBH v. Auto. Components Holdings, LLC*, No. 2:10-cv-14097-SFC, 2011 WL 5307797, at \*7 (E.D. Mich. Nov. 3, 2011) (applying *Therasense*’s “but for” materiality standard in ruling on motion to dismiss inequitable conduct counterclaims).<sup>8</sup>

Moreover, *Therasense* reaffirmed that district courts “may not infer intent solely from materiality.” 649 F.3d at 1290 (“A district court should not use a ‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.”); *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011).<sup>9</sup>

**A. Sufficiency of allegations regarding materiality**

The materiality element of inequitable conduct requires the pleader to “identify which claims, and which limitations in those claims, the withheld references are relevant to, and where

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<sup>8</sup> The but for materiality requirement applies except in cases of affirmative egregious misconduct, in which case such misconduct is material in and of itself. *Therasense*, 649 F.3d at 1292 (“When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.”) (citing cases).

<sup>9</sup> The Court rejects TMC’s argument that Mylan must, at the pleading stage, make an initial showing from which it can be plausibly inferred that “the intent to deceive is the single most likely explanation for the non-disclosure.” As the *Exergen* decision makes clear, “[i]n contrast to the pleading stage, to prevail on the merits, the accused infringer must prove both materiality and intent by clear and convincing evidence. Whereas an inference of deceptive intent must be reasonable and drawn from a pleading’s allegations of underlying fact to satisfy Rule 9(b), this inference must be ‘the *single most reasonable* inference able to be drawn from the evidence to meet the clear and convincing standard.’” *Exergen*, 575 F.3d at 1329, n.5 (citing *Star Scientific*, 537 F.3d at 1365-66). Nothing in *Therasense* alters this distinction.

in those references the material information is found—i.e., the ‘what’ and ‘where’ of the material omissions.” *Exergen*, 575 F.3d at 1329. Moreover, the pleading must allege facts to support a plausible inference that the withheld information is “but for” material—in other words, that the “PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *See Therasense*, 649 F.3d at 1291-93.<sup>10</sup>

TMC argues that Mylan fails to adequately identify the specific claim limitations to which the withheld references are relevant. The Court disagrees. Having carefully reviewed Mylan’s allegations, as well as both parties’ arguments in support of their respective positions, Mylan satisfies Rule 9(b)’s heightened pleading requirement with respect materiality as to all three instances of alleged inequitable conduct.

Mylan satisfies *Exergen*’s requirement of “identify[ing] which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e. the ‘what’ and ‘where’ of the alleged misrepresentations and omissions.” 575 F.3d at 1329. Specifically, Mylan alleges that “all patent claims of the patents-in-suit are directed toward ‘pharmaceutical batches’ of Angiomax having either (1) ‘a maximum impurity level of Asp<sup>9</sup>-bivalirudin that does not exceed about 0.6% as measured by HPLC;’ or (2) ‘a maximum reconstitution time that does not exceed about 42 seconds and a maximum total impurity level that does not exceed about 2% as measured by HPLC’” and that “[n]one of the claims of the patents-in-suit would have issued but for these misrepresentations or omissions.” (*Id.* ¶¶ 84, 107 (emphasis added).) In other words, Mylan asserts that Krishna’s and Musso’s omissions and misrepresentations are relevant to *each and every claim* (and, by

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<sup>10</sup> TMC does not dispute that Mylan has adequately alleged “but for” materiality.

necessity, all limitations of those claims) of the patents-in-suit because it alleges that none of the claims (and therefore none of the claim limitations) would have issued if TMC would have provided the omitted information to the PTO.

This assertion is supported by Mylan's allegation that the Patent Examiner, on three separate occasions, previously rejected *all proposed claims*, reasoning that they were obvious and/or anticipated in view of the prior art in that the prior art products "necessarily have *all the characteristics and functionalities* of the instantly claims products." (R. 62 ¶ 89 (emphasis added).) TMC allegedly overcame these rejections by relying specifically on the alleged differences between the Old Compounding Process and the New Compounding Process to support its argument to the PTO that the claimed Angiomax® was different from, and patentable over, prior art Angiomax®. (*Id.* ¶ 106.)

Furthermore, Mylan's detailed allegations identify "where" in the omitted documents the material information is found. *See, e.g.*, ¶¶ 87-89, 104-06, 108, 111-15, 121-22. Indeed, Mylan's counterclaim allegations are replete with citations to specific portions of specific documents, referenced by Bates number, that have been produced in this litigation and the Delaware Litigation. Mylan has met its heightened burden.

**B. Sufficiency of allegations regarding intent to deceive**

In *Exergen*, the Federal Circuit held that in order to adequately allege intent, the pleader must name the individual(s) associated with the filing or prosecution of the application "who both knew of the material information and deliberately withheld or misrepresented it." 575 F.3d at 1329. With respect to the first intent requirement, the court cautioned that "[o]ne cannot assume that an individual, who generally knew that a reference existed, also knew of the specific

material information contained in that reference.” *Id.* at 1330 (citing *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)). With respect to the second, the court held that a “deliberate decision to withhold a known material reference” is a “necessary predicate for inferring deceptive intent.” *Id.* at 1331 (citing *Molins*, 48 F.3d at 1181). Moreover, district courts cannot infer intent from materiality. *Therasense*, 649 F.3d at 1290.<sup>11</sup>

TMC argues that Mylan fails to plead any facts that support an inference that Krishna or Musso made a “deliberate decision” to withhold or misrepresent material information. Additionally, TMC argues that Mylan fails to plead an independent basis for intent to deceive, and instead impermissibly asks the Court to infer intent based on materiality. The Court addresses TMC’s arguments with respect to each category of alleged misrepresentations/omissions below.

#### **1. Methods of making Angiomax®**

Mylan alleges that Krishna and Musso “repeatedly misrepresented in the patents-in-suit, and in arguments made to the Patent Examiner” that prior art Angiomax® was different from claimed Angiomax®. Specifically, they argue that prior art Angiomax® was made by the Old Compounding Process, which was “characterized by (1) adding base ‘either all at once, or rapidly in multiple portions’ and (2) ‘inefficiently mixing’ the compounding solution by a paddle

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<sup>11</sup> For this reason, Mylan’s argument that the Court may “infer deceptive intent from the high materiality of the misrepresentations” is incorrect. (R. 68 at 9-10.) That said, and as TMC concedes (R.77 and 78 at 7), whether Musso and Krishna knew that the information they allegedly misrepresented or withheld from the PTO is relevant to whether they acted with the requisite intent. *See Therasense*, 649 F.3d at 1296 (“On remand, the district court should determine whether there is clear and convincing evidence demonstrating that [the individuals] knew of [the prior art], *knew of their materiality*, and made the conscious decision not to disclose them in order to deceive the PTO.”) (emphasis added).

mixer ‘operat[ing] at a rate of between about 400 rpm and 800 rpm.’” (R. 62 ¶ 104.) Mylan avers that Krishna’s and Musso’s representations were incorrect because, as explained in the 2005 Report, under the Old Compounding Process, “(1) base was sometimes pumped in through ‘a drain hose’ or ‘pump,’ as opposed to either ‘all at once, or rapidly in multiple portions,’ and (2) the paddle-mixer speeds were ‘increased from a range of 400-600 RPM to a range of 900-1300 RPM’ to improve mixing.” (*Id.* ¶ 105.)

Contrary to TMC’s assertions, Mylan has set forth sufficient facts from which the Court may reasonably infer that Krishna and Musso knew about the omitted and misrepresented information regarding methodology and knew the materiality of such information. *See Exergen*, 575 F.3d at 1329. The omitted methods were described in the 2005 Report, a copy of which was emailed to TMC in January 2006—approximately two and a half years before TMC and/or Krishna and Musso filed applications for the patents-in-suit. The 2005 Report explained that the Example 4 process required that “the mix rate for the two mixers in Vessel #3 is to be increased to aid dispersion of the [base]. . . from a range of 400-600 RPM to a range of 900-1300 RPM” and that “BVL formulators have historically employed different means of adding the [base],” including “by a drain hose.” (*Id.* ¶ 108.) Additionally, a copy of the 2005 Report was produced from Musso’s files in this litigation. (*Id.*) That copy contains “numerous handwritten annotations, and the word “key” appears in the margin next to the words “three main methods.” (*Id.*) Those facts indicate that Musso read the 2005 Report and was aware of the information contained in that report. Moreover, Mylan alleges that the July Meeting Summary, which Musso authored, acknowledged that BVL operators had historically used three methods of adding base during the compounding process—“by a pump, poured in or dumped at variable rates.” (*Id.* ¶¶ 65,

108.) The July Meeting Summary was produced in this litigation from Krishna's files. (*Id.* ¶ 66.) Therefore, it is reasonable to infer that Musso and Krishna knew about the methodology information from the July 15 Meeting Summary.

Mylan has also alleged sufficiently that Krishna and Musso knew that these omissions and misrepresentations were material. The Patent Examiner, on three separate occasions, previously rejected the claims of the patents-in-suit (for which Musso and Krishna are the applicants) based on a finding that the claimed Angiomax® did not differ from the prior art bivalirudin products. (R. 62 ¶ 89.) In an attempt to distinguish the claimed Angiomax®, Krishna and Musso allegedly submitted the methodology information (and left out key information) in their arguments to the PTO that the New Compounding Process differed from the Old Compounding Process. (*Id.* ¶¶ 90-109.) These allegations support an inference that they knew that the Patent Examiner would rely on their arguments regarding the differences in the processes in deciding whether to issue the patents.

Finally, Mylan alleges sufficient facts from which the Court may reasonably infer that Krishna and Musso specifically intended to deceive the PTO. By telling the PTO that adding a base by a "feed tube extended from a peristaltic pump" was part of the New Compounding Process, Musso and Krishna contradicted Musso's *own previous writings*, which indicated that the Old Compounding Process involved adding base through a pump. (*Id.* ¶¶ 65, 108.) This is not a case where "the applicant [allegedly] knew of a reference, should have known of its materiality, and decided not to submit it to the PTO." *See Therasense*, 649 F.3d at 1290-91 (holding that gross negligence is insufficient to justify an inference of intent to deceive). Rather, these allegations support that Krishna and Musso deliberately decided to withhold and

misrepresent information showing that portions of the Old Compounding Process were the same or substantially similar to the New Compounding Process because they knew that the Patent Examiner had previously rejected the applications (on three separate occasions) on the grounds that the claimed product did not differ from the prior art. Such allegations of circumstantial facts indicating specific intent are sufficient. *See Therasense*, 649 F.3d 1276 (“Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.”).

TMC analogizes this case to *Edge Capture L.L.C. v. Barclays Bank PLC*, No. 09 CV 1521, slip op. (N.D. Ill. Aug. 30, 2011) (Norgle, J.) (unpublished), in which the court granted the plaintiff’s motion to dismiss the defendants’ inequitable conduct counterclaims and affirmative defenses on the ground that they failed to adequately allege intent to deceive.<sup>12</sup> The court found that the defendants’ allegations that the inventors knew about prior art, were, without more, insufficient to allege intent to deceive. *Id.* at 24. As explained in detail above, however, the facts of this case are different because Mylan has alleged much more than that Krishna and Musso were merely aware of prior art. For similar reasons, TMC’s reliance on *Human Genome Sci., Inc. v. Genentech, Inc.*, No. 2:11-cv-6519-MRP, slip op. (C.D. Cal. Dec. 9, 2011) is also inapposite. There, the court dismissed an inequitable conduct counterclaim, finding that the defendants had failed to allege intent to deceive in part because they had failed to allege facts from which the court could reasonably infer that the plaintiff knew the materiality of the nondisclosed information. Here, in contrast, Mylan has pled numerous facts from which the

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<sup>12</sup> TMC incorrectly states throughout its briefing that “this Court” reached the decision in *Edge Capture*. Judge Norgle issued that opinion.

Court may reasonably infer that Krishna and Musso knew of the materiality of all of their alleged misrepresentations and omissions.

## **2. Experimental results**

Mylan alleges that Krishna and Musso repeatedly misrepresented in the patents-in-suit and in arguments they made to the Patent Examiner that claimed Angiomax® “consistently ha[d] lower levels of impurities” and “consistently ha[d] shorter reconstitution times” than prior art Angiomax®.<sup>13</sup> According to Mylan, these representations were false because information that Krishna and Musso withheld from the PTO showed that over 85% of both prior art Angiomax® and claimed Angiomax® batches had impurity levels and reconstitution times “less than or equal to the characteristics recited in at least the independent claims of the patents in suit.” (*Id.* ¶ 113 (citing specific examples).) Furthermore, “with respect to total impurities, there were more claimed Angiomax® batches than prior art Angiomax® batches that exceeded the total-impurity limitations of the patent claims.” (*Id.*)

Additionally, Krishna and Musso allegedly repeatedly misrepresented that claimed Angiomax® had “a maximum impurity level of Asp<sup>9</sup>-bivalirudin of about 0.6%,” “a maximum reconstitution of about 42 seconds,” and “a maximum amount of total impurities of about 2.0%,” “for all batches for formulations made by the new process.” (*Id.* ¶ 112.) These representations, according to Mylan, were false because at least one of the Angiomax® batches made by the new compounding process has (1) maximum impurity levels of Asp<sup>9</sup>-bivalirudin exceeding the claimed limit of about 0.6%, (2) maximum total impurity levels exceeding the claimed limit of

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<sup>13</sup> The patents-in-suit define the term “consistently” to mean that “about 85% of the pharmaceutical batch(es) or pharmaceutical formulation(s) have a specific characteristic.” (R. 62 ¶ 111 (citing ‘727 Patent at 13:13-17).)

about 2.0%, or (3) maximum reconstitution times exceeding the claimed limit of about 42 seconds. (*Id.* ¶ 114 (citing specific lots with data).)

Mylan has sufficiently alleged that Musso and Krishna knew about the experimental results because documents that TMC produced from Musso and Krishna's files specifically described the omitted experimental results. (R. 62 ¶ 117 (listing specific documents).) Moreover, given Krishna's and Musso's alleged involvement with both the Old and New Compounding Processes, as well as their involvement in the applications of the patents-in-suit, it is reasonable to infer that they were aware of the experimental results.

For the same reasons articulated above with respect to methodology, Musso and Krishna also knew that the omitted and misrepresented information was material. Furthermore, Mylan has sufficiently alleged that Krishna and Musso specifically intended to deceive the PTO by withholding and misrepresenting information about experimental results. The withheld information, which was described in the same document that TMC has admitted included the experimental results that Musso and Krishna in fact submitted to the PTO, directly contradicted the statement Musso and Krishna made to the PTO that "all batches or formulations made by the new process" had impurity and reconstitution levels not exceeding the claim limitations. (R. 62, ¶¶ 91, 112-114.) Accordingly, accepting Mylan's allegations as true, Krishna and Musso disclosed experimental results that supported their position to the PTO, but failed to disclose contradictory experimental results, even though those results were contained in the *same document* as the favorable results. This fact, combined with Krishna and Musso's knowledge that the Patent Examiner had rejected their claims on three previous occasions on the grounds that the new process was the same or substantially similar to the old process, sufficiently

supports a reasonable inference of specific intent to deceive.

### **3. Failure to disclose prior art**

Mylan alleges that Krishna and Musso engaged in a third instance of inequitable conduct before the PTO by failing to disclose material prior art and by materially misrepresenting that they were original, first, and joint inventors of the claimed subject matter. (*Id.* ¶ 119.)

Specifically, Mylan asserts that Krishna and Musso did not disclose that BVL operators previously invented the claimed New Compounding Process on or before July 14, 2006 and misrepresented to the PTO in their 37 C.F.R. § 1.63 declarations that “[they] believe[d] [they were] original, first, and joint inventor[s] . . . of the subject.” (*Id.* ¶ 120.) Mylan supports its contention by pointing to the 2005 Report, which disclosed that BVL operators previously had added base by “a drain hose” forced into the compounding solution, and in order to “aid dispersion,” the operators increased mixing speeds “to a range of 900-1300 RPM.” (*Id.* ¶ 121.) Musso’s July Meeting Summary also disclosed that BVL operators suggested improving the compounding process by adding base through a dip tube so that it is dispersed in the bottom of the tank and by increasing the stir speed prior to adding the base. (*Id.* ¶ 122.)

Although it is a closer call, accepting Mylan’s factual allegations as true, Mylan has adequately alleged intent with respect to Musso and Krishna’s failure to disclose prior art. Mylan’s allegations support a reasonable inference that Krishna and Musso knew that BVL operators created the ideas of (1) adding base by a feed tube extended from a peristaltic pump and (2) efficiently mixing the compounding solution at speeds of 1000 and 1300 rpm on or before July 14, 2006. Krishna and Musso knew this information because Musso attended a meeting on July 14, 2006 where such information was discussed, and he wrote a summary of that

meeting, which included the information, the following day. (*Id.* ¶ 124.) Krishna also knew about that information because, as noted above, a copy of the July Meeting Summary was produced from his files in this case. The information was also contained in the 2005 Report, the contents of which both Krishna and Musso were allegedly aware.

Musso and Krishna also understood that their representations regarding inventorship were material to patentability, in part because they signed 37 C.F.R. § 1.63 declarations stating that “[they] believe[d] [they were] original, first, and joint inventor[s] . . . of the subject matter which is claimed and for which a patent [was] sought on the invention.” (R. 62 ¶ 120.) Moreover, as Mylan alleges, the PTO cautioned Krishna and Musso to fully disclose inventorship details. (*Id.* ¶ 125 (alleging that the PTO cautioned Krishna and Musso that “Applicant is advised of the obligation under 37 C.R.E. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. 102(e), (f), or (g) prior art under 35 U.S.C. § 103(a).”).) It is axiomatic that a Patent Examiner would not issue a patent to a named inventor if that inventor was not, in fact, the true inventor, and therefore it is reasonable to infer that Krishna and Musso understood the materiality of their inventorship representations to patentability.<sup>14</sup>

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<sup>14</sup> TMC argues that Mylan does not allege that Musso or Krishna “understood the legal requirements for inventorship.” (R. 77 and 78 at 10.) Musso and Krishna had the benefit of sophisticated legal representation during the prosecution of the patents-in-suit, and they also signed a declaration that clearly stated they were the “original, first, and join inventor[s]” of the patents-in-suit. Those facts are sufficient at the motion to dismiss stage to support an inference that Musso and Krishna understood that the inventorship information they supplied to the PTO was false.

Finally, Mylan has adequately alleged that Musso and Krishna specifically intended to deceive the PTO. Musso and Krishna were both allegedly aware that the BVL operators had, as early as 2005, added base through a pump and used high mixing speeds when adding the base to the solution. That fact, combined with the allegation that Musso and Krishna, despite the PTO's warning "to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made," nevertheless failed to tell the PTO that BVL operators created portions of the New Compounding Process, is sufficient to support a reasonable inference that Krishna and Musso made a deliberate decision to withhold the information.

## **II. Unclean Hands**

The "governing principle" of the unclean hands doctrine is "that whenever a party who, as actor, seeks to set the judicial machinery in motion and obtain some remedy, has violated conscience, or good faith, or other equitable principle, in his prior conduct, then the doors of the court will be shut against him in limine; the court will refuse to interfere on his behalf, to acknowledge his right, or to award him any remedy." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244-45, 54 S.Ct. 146 (1933) (quoting Pomeroy, *Equity Jurisprudence* (4th Ed.) § 387). Courts apply the unclean hands doctrine only where the "unclean act" has an "immediate and necessary relation" to the equity that the party seeks in the litigation. *Id.* at 245 (noting that unconscionable acts that do not "affect the equitable relations between the parties in respect of something brought before the court for adjudication" will have no bearing on the unclean hands determination). Moreover, courts have a "wide range" of discretion "in refusing to aid the unclean litigant." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S.

806, 815, 65 S.Ct. 993, 89 L.Ed. 1381 (1945); *see also Keystone*, 290 U.S. at 245 (courts “are not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion”).

**A. Unclean hands affirmative defense**

Applying Illinois law, TMC argues that Mylan’s unclean hands affirmative defense fails as a matter of law for two reasons. First, Mylan does not allege that TMC’s purported misconduct was directed at Mylan. Second, TMC does not allege a nexus between the alleged false listing and whether Mylan’s ANDA infringes the patents-in-suit. *See* R. 66 and 67 at 14 (citing cases).

The Supreme Court in *Keystone* and *Precision* addressed the doctrine of unclean hands in the context of patent cases. Pursuant to that authority, an unclean hands defense requires 1) an unconscionable act by the “unclean” litigant; and 2) an “immediate and necessary relation” between that act and the equity that the party seeks in the litigation. *Keystone*, 290 U.S. 244-45; *see also Precision Instrument*, 324 U.S. at 815 (“Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the [unclean hands] maxim by the chancellor.”). TMC does not, at least for purposes of its motion, dispute the first requirement.<sup>15</sup> Therefore, the only issue is whether Mylan has alleged an “immediate and necessary relation” between TMC’s conduct before the FDA and this litigation.

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<sup>15</sup> TMC’s failure to dispute unconscionability at this stage in the litigation is not a bar to raising it on the merits at a later date.

Mylan has met this burden. It alleges that in listing the patents-in-suit in the “Orange Book,” TMC certified to the FDA that the patents cover the “approved drug product,” i.e., Angiomax, and that the process claimed in the ‘343 Patent was novel. (R. 62 ¶ 128.) Mylan further alleges that TMC filed certifications to list the patents-in-suit in the Orange Book knowing that it had obtained the patents-in-suit after misrepresenting information in front of the PTO. (*Id.*) Critical to the nexus between TMC’s conduct before the FDA and its claims against Mylan is that TMC allegedly obtained jurisdiction to file this lawsuit based on those allegedly false certifications.<sup>16</sup> (*Id.* ¶ 130.)

In this respect, the Court agrees with the Special Master in the Delaware Litigation that, “assuming *arguendo* that the patents-in-suit should not have been listed in the Orange Book in the first place, [Mylan] would not have been required to make a certification to the FDA regarding those patents in connection with submitting its ANDA, and thus, [TMC] would not have had a basis to file [this action] against [Mylan] under 35 U.S.C. § 271(e)(2)(A).” *See* R. 73-1, Lee Decl. Ex. 1, *The Medicines Co. v. Teva Parenteral Meds.*, C.A. No. 09-750-ER, Special Master’s Am. Rep. and Recommendation at 49 (D. Del. June 23, 2011), at 49. Therefore, Mylan has alleged an “immediate and necessary relation” between TMC’s alleged misconduct and this litigation. *Keystone*, 290 U.S. 244-45.

TMC insists that the Court must dismiss Mylan’s affirmative defense because it does not allege that TMC’s misconduct was directed specifically at Mylan. This argument is unpersuasive. TMC has provided no basis why this Court can or should ignore Supreme Court precedent addressing the unclean hands doctrine in patent cases, which are governed by federal

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<sup>16</sup> *See* footnote 2, *supra*, for a discussion of the ANDA approval process.

law, in favor of applying a more restrictive interpretation of the unclean hands doctrine followed by some Illinois courts. *See MPC Containment Sys., Ltd. v. Moreland*, No. 05 C 6973, 2008 WL 1775501, at \*4 (N.D. Ill. Apr. 17, 2008) (citing Illinois law); *but see Gambino v. Boulevard Mortg. Corp.*, 398 Ill. App.3d 21, 922 N.E. 2d 380 (Ill. App. 1st Dist. 2009) (unclean hands doctrine “bars relief when the party seeking that relief is guilty of misconduct in connection with the subject matter of the litigation” and imposing no requirement that the misconduct is directed at the opposing party). This Court is not alone among Illinois courts in applying *Keystone* to unclean hands defenses in patent cases. *See Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp.2d 884, 900 (N.D. Ill. 2006) (“The doctrine of unclean hands can apply where a plaintiff engages in misconduct related to a patent at issue.”); *Ristvedt-Johnson, Inc. v. Brandt, Inc.*, 805 F. Supp. 549, 555 (N.D. Ill. 1992); *Nat’l Presto Indus., Inc. v. Black & Decker (U.S.) Inc.*, 760 F. Supp. 699, 702 (N.D. Ill. 1991) (“In a patent case, the misconduct should ‘bear upon the validity of the patent or defendant’s infringement of the patent for the unclean hands defense to be available.’” (quoting *Southwire Co. v. Essex Grp., Inc.*, 220 U.S. P.Q. 1053 (N.D. Ill. 1983))). Moreover, Mylan’s allegations are sufficient even under the more restrictive standard that TMC proposes because, as explained in detail above, TMC’s allegedly fraudulent conduct had a direct impact on Mylan and other potential ANDA applicants with respect to the patents-in-suit.

**B. Unclean hands counterclaims**

Mylan asks the Court to issue a declaratory judgment of unenforceability of the ‘727 and ‘343 Patents due to TMC’s unclean hands. The parties agree that a finding of unclean hands does not render a patent unenforceable. *See Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1378 (Fed. Cir. 2001) (“The doctrine of unclean hands does not reach out to extinguish a

property right based on misconduct . . . to enforce a right.”). Instead, a finding of unclean hands bars the unclean litigant from obtaining the equitable relief it seeks in the particular action at hand. *See id.* at 1374. Indeed, this is the precise relief available to Mylan if it succeeds in proving its unclean hands affirmative defense, which, as explained above, remains pending. Because, under Federal Circuit precedent, the Court does not have the authority to declare the patents-in-suit unenforceable on the grounds of unclean hands, the Court dismisses Mylan’s unclean hands counterclaims.<sup>17</sup>

### CONCLUSION

For the reasons set forth above, the Court grants TMC’s motion in part and denies it in part. Specifically, the Court dismisses, with prejudice, Mylan’s Ninth and Tenth Counterclaims for a declaratory judgment of unenforceability due to unclean hands. The Court denies TMC’s motion as to Mylan’s inequitable conduct counterclaims and affirmative defenses and as to Mylan’s unclean hands affirmative defenses. TMC must answer Mylan’s counterclaims by March 7, 2012.

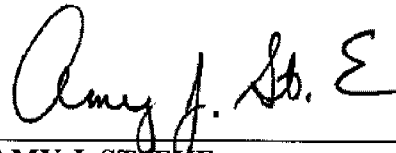
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<sup>17</sup> Because the Court has already determined that Mylan’s unclean hands counterclaims are subject to dismissal, the Court need not address TMC’s argument that such counterclaims are not legally cognizable.

Additionally, the Court orders Mylan to file a revised public version of its First Amended Answer, Separate Defenses and Counterclaims, and orders Mylan and TMC to file revised public versions of their briefs related to TMC's motion to dismiss and strike, consistent with the Court's guidance in footnote 3 of this Memorandum Opinion and Order, by February 29, 2012.

**Date:** February 15, 2012

**ENTERED**

A handwritten signature in black ink, appearing to read "Amy J. St. Eve", written over a horizontal line.

**AMY J. ST. EVE**

**United States District Court Judge**